NDA 20-708/S-010

TAP Pharmaceutical Products, Inc.
Attention: Jessie Y. Lee, Ph.D.
Senior Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

1 MAR 2001

Dear Dr. Lee:

Please refer to your supplemental new drug application dated November 14, 2000, received November 15, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
20-708	S-010	Lupron® Depot 3-Month 11.25 mg (leuprolide acetate for depot suspension)

This "Changes Being Effected" supplemental new drug application provides for revision of the storage conditions for the drug product in the package insert per ICH guidelines from:

"No refrigeration necessary. Protect from freezing."

To:

"Store at 25°C (77°F); excursions permitted to 15-30° C (59-86°F). [See USP Controlled Room Temperature]"

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 14, 2000). Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader for the
Division of Reproductive and Urologic Drug Products, (HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research